IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

OPHTHALMIC FLUID DISPENSER

Field Of The Invention

The invention pertains to delivery of ophthalmic fluids to the eye and more particularly to a device for dispensing ophthalmic fluid in small controlled doses.

Background Of The Invention

Ophthalmic products are available for treatment of various conditions. For example, the treatment of glaucoma requires frequent daily administrations of certain ophthalmic compositions having the desired pressure-relieving action. Ophthalmic fluids also are used to relieve eye strain and irritation caused by smog, allergens such as pollen and dust, smoking, and swimming, etc. In the application of certain medical preparations, it is necessary that the fluid be delivered in a fairly well-defined volume since an excessive dosage may result in improper physiological effects. Another requirement is that the need to properly target the dose of ophthalmic medication. A contributing factor in requiring the delivery of a specified dose is the matter of cost in the case of expensive medications. Many ophthalmic fluids may be self-administered by the user. Accordingly in the case of self-treatment, a further consideration is the need to achieve delivery to the targeted eye without the patient having to assume a strained body, head or hand position, since such a strained posture may result in forced errors. Another important factor to consider in facilitating patient self-treatment and operator-assisted treatment is that ophthalmic medications are commonly sold in small bottles which are not designed to function as controlled dosage applicators.

Therefore there is a need for dispenser/applicator device that is adapted to accept conventional ophthalmic product bottles, with the containers being easy to install and replace, and with the device filling control being unaffected by the size of the ophthalmic product container. An important consideration in using an applicator device to administer ophthalmic products to the eye is the need to maintain a sterile condition in the applicator.

A number of different applicator devices are known for dispensing an ophthalmic product to the eye of a patient. Such known devices suffer from various limitations. Certain devices for small volumes are based either on drop or on spray delivery principals. Drop applicators rely on impact by gravity, but common designs give little control over the administration of ophthalmic products. Certain devices are difficult to operate except with proper orientation of the device. Spray applicators rely on a shower. While prior spray applicators tend to be independent of applicator orientation and give a distributed spray, they are limited in controlling the amount that is dispensed. In some devices contamination can result from contaminants being drawn into the applicator after some product has been dispensed. Accordingly, there remains a need for a fluid eye applicator better meeting the demands for dispensing ophthalmic medications in controller amounts.

Object And Summary Of The Invention

A main object of the invention is to provide a dispenser for applying an ophthalmic product to the eye which permits patient self-treatment without requiring the patient to have exceptional mechanical dexterity in order to achieve the desired dosage or to deliver it to the targeted eye.

Another object of the invention is to provide an eye fluid applicator that is designed to dispense a predetermined dose of an ophthalmic product in the form of a narrow spray.

Still another object is to provide an eye fluid applicator which is adapted for connection to a bottle of an ophthalmic solution and to dispense that solution from the bottle in limited amounts and in a manner which avoids contacting the eye, thereby eliminating the possibility of contamination of the contents of the device in the case where an eye is infected or contagious.

A further object of the invention is to provide a dispenser for ophthalmic medications which permits self-treatment by the patient and does not require the patient to assume a strained body position in order to apply the ophthalmic medication.

A more specific object is to provide a device of the character described which may be made of a plastic material, has a relatively low cost, and is designed to reliably dispense a limited quantity of ophthalmic solution each time it is operated.

These and other objects are achieved by a device which essentially comprises a body that is adapted to be attached to the mouth of a bottle containing a quantity of an ophthalmic fluid, means for receiving and holding a limited quantity of ophthalmic fluid from the bottle, and means for dispensing that limited quantity of ophthalmic fluid to the eye of a patient in the form of a spray. The amount of fluid that is dispensed is metered by means of a member that has a cavity which is movable from a first position in which it is disposed to receive fluid from the container and a second position in which it allows the fluid to pass to a holding chamber, and the device further includes means for removing fluid from the holding chamber in the form of a spray, with the spray delivery being accomplished by means of an air stream injected into the holding chamber.

Other features and advantages of the invention are described in or rendered apparent by the following detailed description of a preferred embodiment of the invention, which is to be considered together with the accompanying drawings.

The Drawings

Fig. 1 is a side view in elevation of a device constituting a preferred embodiment of the invention;

Fig. 2 is a perspective view in elevation of the same device;

Fig. 3 is an exploded perspective view of the same device;

Fig. 4 is a longitudinal center line sectional view in elevation of the same device;

Fig. 5 is a longitudinal sectional view taken along line 5-5 of Fig. 4;

Fig. 6 is a longitudinal sectional view of the body of the same device, taken along the plane identified by line 6-6 in Fig. 4;

Fig. 7 is a cross-sectional view taken along line 7-7 of Fig. 1;

Fig. 8 is an enlargement of a portion of Fig. 7 illustrating details of the orifice insert and the metering member;

Fig. 9 is an enlargement of a portion of Fig. 4;

Figs. 10A and 10B are enlargements of a portion of Fig. 5;

Fig. 11 is a cross-sectional view taken along lines 11-11 of Fig. 6; and

Fig. 12 is a longitudinal sectional view in elevation like Fig. 4 but showing the device with a bottle attached and with the device in discharge position.

Specific Description Of The Preferred Embodiment

Referring to Figs. 1-7, a dispenser device constituting a preferred embodiment of the present invention comprises a housing in the form of a body 2 having an axial cavity 4 with an enlarged outer end characterized by a screw thread 6 for use in attaching a bottle 8 (Fig. 12) containing an ophthalmic liquid (not shown). The inner end of cavity 4 is intersected by a diametrically-extending bore 12, resulting in the formation of a hole 13 (Figs. 1 and 2) at the bottom cavity 4. The diameter of hole 13 is equal to

or slightly greater than that of metering cavity 18 described hereinafter. Preferably, but not necessarily, the outer surface of body 2 is provided with an outwardly projecting circular boss 14 at each end of bore 12. The outer face of each boss is flat and acts as a bearing surface for the operating lever 86 described below.

Mounted within bore 12 is a metering member 16 in the form of a cylindrical shaft having a cavity 18 located intermediate its ends. Cavity 18 acts as a metering and transfer chamber, being sized to accommodate a predetermined volume of liquid. Preferably cavity 18 has a generally hemispherical shape, but it may have some other shape instead. By way of example but not limitation, cavity 18 may have a diameter of about 2 mm measured horizontally, i.e. in a plane extending parallel to the axis of metering member 16, and a depth of about 1 mm, thereby providing a volume of about 10 to 12 microliters (μl), depending on the slope of surface defining the cavity. Cavity 18 is located so that it can be moved by rotation of member 16 into alignment with hole 13.

Referring to Figs. 4-6, the lower end of body 2 is formed with a cylindrical cavity 30 and two blind holes 32A and 32B that form extensions of cavity 30. Cavity 30 is axially aligned with cavity 4. Blind holes 32A and 32B are located eccentric to the axis of housing 2.

Referring to Figs. 4, 7-9 and 11, body 2 also is provided with a radial bore 20 that extends perpendicular to bore 12 and the axis of cavity 4. The inner portion of bore 20 may have a constant diameter, but preferably it is tapered down to a diameter closer to that of cavity 18 of metering member 16, as shown in Fig. 9. The outer portion of bore 20 has a counterbore 21 to accommodate an orifice insert 22. Orifice insert 22 is formed with a small diameter orifice 24 at its outer end, and an enlarged flared counterbore 26 at its inner end that preferably forms a smooth continuation of the inner portion of bore 20. By way of example but not limitation, orifice 24 may have a diameter of about 0.6 to about 0.7 mm. Bore 20 and the center axis

of orifice insert 22 extend along a line that intersects at a right angle the portion of metering member 16 that has the cavity 18. Orifice insert 16 also has two side openings 28A and 28B (Fig. 8) that are aligned with each other parallel to bore 12. As illustrated in Figs. 6, 8 and 11, the counterbore 21 intersects blind holes 32A and 32B a selected distance below their inner ends. As seen best in Fig. 8, the side openings 28A and 28B in orifice insert 22 are located so that they are aligned in a plane that includes the center axis of blind holes 32A and 32B, with the result that air can flow via openings 28A and 28B between the upper ends of blind holes 32A and 32B and the counterbore 26 of insert 22.

Referring to Figs. 4, 5 and 9, mounted in the opening 30 is a cup-shaped member 40 having a side wall 42 and an end wall 44. The latter has two openings that are provided with cylindrical extensions 46A and 46B that extend into and make a close fit with blind holes 32A and 32B. As seen best in Figs. 10A and 10B, these tubular extensions terminate even or slightly below the lowermost portion of side openings 28A and 28B of orifice insert 22, so that air can pass between tubular extensions 46A and 46B and openings 28A and 28b respectively. The upper ends of tubular extensions 46A and 46B are closed off by valve means comprising valve members 48A and 48B and leaf springs 52A and 52B that are formed integral with the valve members. The valve members have round bottom surfaces that are sized and shaped to seat on and close off the upper ends of tubular extensions 46A and 46B. Valve members 48A and 48B and their leaf springs may be molded of a light weight plastic material. The free ends of the leaf springs engage the side walls of blind holes 32A and 32B. The leaf springs function to hold the valve members 48A and 48B in closed position against the upper ends of tubes 46A and 46B, as shown in Fig. 5. However, the leaf springs are relatively weak, having a stiffness just sufficient to hold valve members 46A and 46B in closed position, but low enough to permit the valve members to pivot up off of the tubes to the

position shown in Fig. 10B under the influence of air forced up into the tubes, whereby to allow air streams to pass into the orifice insert via its side openings 28A and 28B.

Referring to Figs. 4 and 12, cup shaped member 40 is formed with a center post 56 depending form its end wall 44. Telescopically engaged with and protruding into cup-shaped member 40 is a cup-shaped piston member 58 characterized by a tubular side wall 60 and a bottom wall 62. The latter also has a center post 64 aligned with post 56. A compression spring 66 surrounds posts 56 and 64 and acts to urge piston member 58 outwardly of cup-shaped member 40, i.e., away from cavity 4. The inner end of piston member 58 is provided with a peripheral bead or flange 68 and the cup-shaped member 40 is provided with an internal bead 70 that acts as a stop for bead 68, thereby limiting outward movement of the piston 58. One or more small vent ports 72 (Fig. 4) are formed in side wall 60 of piston member 58 to allow air to bleed into the piston when the latter is in its extended (at-rest) position (Figs. 1-3, 4 and 5). Ports 72 are located adjacent to the inner ends of piston member 58.

As seen in Figs. 1-3 and 7, the metering member 16 is provided with square extensions 80 at its opposite ends. These extensions act as keys for making a locking engagement with square holes 82 in two connection members 84A and 84B that are attached to and are movable by a curved lever 86. The flat outer faces of bosses 14 are engaged by and act as bearing surfaces for connection members 84A and 84B as they are rotated by manipulation of lever 86. The latter comprises a pair of arms 88A and 88B that are curved and are attached to a curved cross member 90. Lever 86 is used to rotate metering member 16 from a first position in which the cavity 18 is aligned with the hole 13 at the bottom of cavity 4 and a second position in which the cavity 18 is aligned with radial bore 20 and the center axis of orifice insert 22.

Referring now to Fig. 12, there is shown a bottle 8 of the type used to contain an ophthalmic solution. The bottle has a cylindrical discharge section 92 that is terminated by a tapered nozzle section 94 having a small discharge opening 96 at its tip. Typically the interior diameter of nozzle section 94 varies from about 4 to about 5 mm. nearest the bottle to a diameter of approximately 2 mm. at opening 96. Tubular discharge section 92 is provided with an exterior screw thread 98 for mating with a screw cap (not shown). The screw thread 6 of cavity 4 is designed to mate with screw thread 98, whereby the bottle and the applicator device may be coupled together by a screw connection as shown in Fig. 12. The shape and size of cavity 4 is set so that it will accommodate nozzle section 94 and so that discharge opening 96 will be aligned with and located in proximity to hole 13 and metering member 16 when the bottle and applicator device have been connected as shown.

Preferably, but not necessarily, the body 2 has a tapered depressed surface 33 surrounding the outer end of radial bore 20 and orifice insert 22 is sized so that its outer end is substantially flush with the center (innermost) section of depressed surface 33. Preferably also the outer end of face of insert 22 has a concave shape so as to form a continuation of depressed surface 33, as shown in Figs. 8 and 9. Recessing the insert 22 in body 2 assists in keeping orifice 24 clean. The depressed surface 33 surrounding the orifice 24 is advantageous for self-medicating uses, since that surface makes it easier to aim the device so as to assure the ophthalmic fluid expelled from orifice 24 is directed at the user's eye.

Operation of the above-described device is straightforward. Assume that the applicator device has been screwed onto a bottle 8 containing an ophthalmic solution as shown in Fig. 12 and that lever 86 is in the raised position shown in Figs. 1 and 2, so that metering chamber 18 is aligned with cavity 4 (as shown in Fig. 4). If the device is oriented so that the bottle is above it, as shown in Fig. 12, ophthalmic liquid will flow out of the bottle by

gravity through hole 13 into cavity 18 in metering member 16. If now lever 86 is pulled down through an angle of 90° (Fig. 12), metering member 16 will be rotated to its second position wherein metering cavity 18 will be aligned with radial bore 20, causing liquid in cavity 18 to fall into and be stored temporarily in a holding chamber that comprises the inner end of bore 20 and the flared counterbore 26 at the inner end of orifice insert 22. At this point, the liquid in the holding chamber will not leak out through the orifice 24 due to the orifice 24 being small enough for surface tension to prevent leakage of the liquid. If thereafter, piston 58 is pushed inwardly, air trapped in the space between cup 40 and piston 58 will be compressed and forced upwardly in tubes 46A and 46B, causing valve members 48A and 48B to pivot to the open position (shown in Fig. 10) and thereby allowing the compressed air to pass from tubular members 46A and 46B to orifice 24 via the side openings 28 in the orifice insert 22. As the air streams pass out of tubular members 46A and 46B into the holding chamber formed by bore 20 and counterbore 26 they merge and have the effect of entraining the ophthalmic liquid in that chamber and expelling it out through the orifice 24, with the entrained liquid being expelled in the form of a spray. Once the liquid has been discharged, piston 58 is released, whereupon spring 66 forces the piston back to its extended position and valve members 48A and 48B drop back to close off tubular extensions 46A and 46B (Fig. 5). The outward (return) movement of the piston has the effect of allowing air to be sucked back into the supply chamber through the small vent ports 72. Metering member 16 may be returned to its standby or fill position (Fig. 2) before or after the piston 58 is operated to expel a dose of liquid. Preferably returning the metering member 16 to its standby or fill position is accomplished before liquid has been expelled from the device. In this connection it is to be noted that when the lever 86 is in the up position (Fig. 2) the metering member 16 may be said to be in the passive or filling position, and when the lever is pulled down 90°, the metering member is

said to be in the active or discharge position wherein a predetermined amount of ophthalmic solution is deposited in the holding chamber ready to be air-expelled via the orifice 24. The device is sized so that when the lever 86 is in its second 90° position (Fig. 12) and engaged with the user's face, the orifice 24 will be approximately 1.25 inches from that person's eye, thereby limiting dispersion of the ophthalmic liquid spray to the area of the intended target, i. e., the user's eye.

The invention has a number of advantages. For one thing, it is designed to hold a conventional form of bottle of the type typically used for storing and dispensing ophthalmic medications. All that is required is to remove the cap from the bottle and screw the device onto the mouth of the bottle. A further advantage is that the device is designed to meter a small quantity, preferably approximately 10 µl, of ophthalmic liquid and to transfer that quantity of liquid to the holding chamber by movement of the metering member. A further advantage is that by appropriately selecting the size of orifice 24, a spray of controlled size can be achieved. The valve members 46A and 46B allow air to flow in the proper direction, closing off backflow of any outside air that may enter trough the orifice 24. Another advantage is that the application housing and certain other parts of the device may be molded of plastic or made of metal.

An important advantage is that the lever 86 may be sized in length so that if its curved end portion 90 is engaged with the cheekbone of the user, the orifice 42 will be spaced a selected distance from the eye calculated to confine the sprayed ophthalmic liquid to within the perimeter of the eye cavity.

The invention is susceptible of a number of modifications. For one thing, the illustrated applicator device may be used with a bottle that does not have an elongate spout as shown at 94 that can extend down to the bottom of cavity 4. In such case, the portion of cavity 4 not occupied by a bottle spout section will serve as a supply chamber for ophthalmic fluid

discharged from container 8, and the cavity 18 will be filled by ophthalmic liquid from that supply chamber. It is contemplated also that the dispenser device may be formed as a part of the bottle, with the bottle being filled in the course of or subsequent to the manufacture of the combination bottle/dispenser device.

It is obvious also that a different form of one-way valve means may be used to close off tubular extensions 46A and 46B. For example, leaf springs 52A and 52B may be replaced by small compression springs. Still other modifications will be obvious to persons skilled in the art.